

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: LEE, Roberta et al.

Serial Number: To Be Assigned

Filing Date: Herewith

Title: EXCISIONAL BIOPSY DEVICE AND METHODS

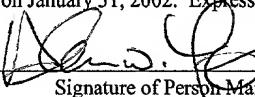
Group Art Unit No.: To Be Assigned

Examiner: To Be Assigned

Att'y Docket: RUBI5531CIPC2

CERTIFICATE OF MAIL

I hereby certify that the within document(s) is/are being deposited with the United States Postal Service "Express Mail Post Office to Addressee" Service under 37 CFR 1.10, and are addressed to the Commissioner of Patents and Trademarks, Box Patent Application, Washington, D.C. 20231, on January 31, 2002. Express Mail Label No. EL 833 860 239 US.



Signature of Person Mailing Document(s)



ALAN W. YOUNG

Printed Name

Honorable Commissioner for Patents  
Washington, DC 20231

**PRELIMINARY AMENDMENT**

Sir:

**IN THE SPECIFICATION:**

Replace the paragraph after "CROSS-REFERENCE TO RELATED APPLICATIONS"

with the following paragraph:

"The present application is continuation of application serial number 09/565,611, which is a Continuation-In-Part of application serial number 09/417,520 filed on October 13, 1999, which is a divisional patent application of US patent application serial number 09/146,743 filed on September 3, 1998, now patent number 6,022,362."

**IN THE CLAIMS:**

Please cancel claims 1-68 of the prior application.

Please add new claims as follows:

69. (New) A method of removing a specimen of breast tissue that is cut from surrounding breast tissue, comprising the steps of:

providing a device that includes a shaft and a tissue collection element coupled to the shaft, the tissue collection element including a thin flexible membrane and being movable from a retracted position to an expanded position;

introducing the device into the breast tissue with the tissue collection element in the retracted position;

expanding the tissue collection element to the expanded position after the introducing step;

moving the tissue collection element to capture the cut specimen;

encapsulating the cut specimen with the thin flexible membrane while maintaining the cut specimen intact and isolating the captured specimen from contact with the surrounding breast tissue;

removing the device from the breast tissue while the specimen remains encapsulated within the thin flexible membrane of the tissue collection element.

70. (New) The method of claim 69, wherein the encapsulating step includes a step of returning the tissue collection element to the retracted position while maintaining the cut specimen intact and encapsulated.

71. (New) The method of claim 69, wherein the providing step is carried out with the tissue collection element including a flexible element to which the thin flexible membrane is attached and wherein the expanding step is carried out with the tissue collection element bowing away from the shaft.

72. (New) The method of claim 69, wherein the moving step includes rotating the shaft.

73. (New) The method of claim 69, wherein the moving step is carried out with the tissue collection element moving along an arc.

74. (New) The method of claim 71, wherein the encapsulating step is carried out with the thin flexible membrane forming a bag.

75. (New) The method of claim 74, wherein the bag is configured to selectively open to capture the cut specimen and close to encapsulate the cut specimen as the tissue collection element bows away from and back toward the shaft, respectively.

76. (New) The method of claim 69, wherein the encapsulating step is carried out with the tissue collection element expanding to a size at least equal to the size of the cut specimen.

77. (New) The method of claim 69, wherein the shaft defines a longitudinal axis and wherein:

the introducing step includes positioning the shaft along side of the cut specimen; and the moving step includes rotating the shaft about the longitudinal axis while moving the tissue collection element from the retracted position to the expanded and back to the retracted position to capture and encapsulate the cut specimen as the shaft rotates.

78. A device configured to remove a specimen of breast tissue that is cut from surrounding breast tissue, comprising:

a shaft, and

a tissue collection element coupled to the shaft, the tissue collection element including a thin flexible membrane, the tissue collection device being movable from a retracted position to an expanded position, the thin flexible membrane being configured to encapsulate the cut specimen while maintaining the cut specimen intact and isolating the captured specimen from contact with the surrounding breast tissue.

79. (New) The device of claim 78, wherein the tissue collection element includes a flexible element to which the thin flexible membrane is attached and wherein the flexible element is configured to selectively bow away from and retract toward the shaft.

80. (New) The device of claim 78, wherein the thin flexible membrane forms a bag .

81. (New) The device of claim 80, wherein the bag is configured to selectively open to capture the cut specimen and close to encapsulate the cut specimen as the tissue collection element bows away from and retracts toward the shaft, respectively.

82. (New) The device of claim 78, wherein the tissue collection element is configured to expand to a size at least equal to the size of the cut specimen.

**REMARKS**

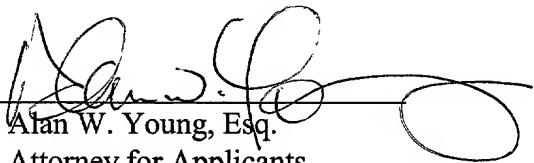
The present application is being submitted as a Rule 53(b) continuation application of USSN 09/565,611,520, filed May 4, 2000. Claims 1-68 of the prior application have been cancelled. Claims 69-82 have been added and are pending in the present application.

Applicant's attorney believes that no new matter has been introduced by this preliminary amendment and that the present application is in condition for an early and favorable examination on the merits. Should the Examiner have any questions, the Examiner has but to contact the undersigned attorney of record at the telephone number indicated below and whatever is required will be done at once.

Respectfully submitted,

YOUNG LAW FIRM, P.C.

By:

  
Alan W. Young, Esq.  
Attorney for Applicants  
Registration No. 37,970  
4370 Alpine Road, Suite 106  
Portola Valley, CA 94028  
Telephone: (650) 851-7210  
Facsimile: (650) 851-7232

Date: January 31, 2002